K021233

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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DEC 0 9 2002

Contact Name: Dipl.-Ing. Christian Abel, Director Quality Management
Name of Device: *aap* Small and Large Cannulated Screw System
Classification Name: Smooth or Threaded Metallic Bone Fixation Fastener
Common/Usual Name: Cannulated Bone Screw
Proprietary Name: *aap* Small and Large Cannulated Screws
Classification: Class II, Smooth or Threaded Metallic Bone Fixation Fastener, CFR Chapter I, Title 21 § 888.3040, # 87 H WC #

Performance Standards: Devices are manufactured according to cGMP's, applicable ASTM requirements, and applicable harmonised standards ISO 9001 / EN 46001.

Material Composition: The *aap* Small and Large Cannulated Screws are manufactured of Titanium Alloy (Ti 6Al 4V E.L.I. = ASTM F136), and 316L Stainless Steel (ASTM F 138)

Intended Use: The *aap* Small and Large Cannulated Screw System is intended for use over a guide pin or wire for bone fracture fixation and bone fragment fixation. *aap*'s washers may be used with the screws in certain applications. Specific indications, which are dependent in part of the diameter of the screw, include: Minimally invasive fracture / joint reconstructions, Additive osteosynthesis for complex joint fractures, Multiple- fragment joint fractures, Femoral neck and femoral head fractures, Femoral supracondylar fractures, Tibial plateau fractures, Simple metaphyseal fractures, Simple epiphyseal fractures, Fractures of the head of the humerus, Fractures of the head of the tibia, Cooper fractures of the tibia, Fractures of the radius, Fractures of the wrist, ankle, elbow and shoulder, Scaphoid fractures and other fractures of the hand, Metatarsal fractures and other fractures of the foot, Ligament fixation of the proximal humerus, Fractures of the acetabulum, Fractures of the dorsal pelvic ring, Condylar fractures, Peadiatric epiphyseal and metaphyseal fractures, Ligament avulsion injuries (Apohysis), Fractures of small joint bones, Malleolar fractures, Navicular fractures, Fractures of the calcaneus and talus, Arthrodesis of the ankle joint, Avulsion fracture and metatarsl V, Fractures of the tarsal region

Device Description: The *aap* Small and Large Cannulated Screws are manufactured of Titanium Alloy (Ti Al6 V4 E.L.I.) and 316 L Stainless Steel. The *aap* Small and Large Cannulated Screws are available in various length and various thread diameters.

Predicate Devices for Substantial Equivalence: *aap* Cannulated Screws, K990776; *aap*'s Bone Screws, K915316; OSTEOTECH Cannulated Screws, K950652; Synthes -Small and Large Cannulated Screw System, K962011 & K963192; HOWMEDICA ASNIS II Guided Bone Screws, K895766; BIODYNAMIC TECHNOLOGIES EZ-Fix ™ Cannulated Screw System. K962706; DePuy Cannulated Bone Screw, K893512; MECRON Cannulated Bone Screws, K810205; ZIMMER MAGNA-Fx & Mini Magna-Fx Cannulated Screw Fixation System (Stainless Steel)

Comparision of Technological Characteristics: The *aap* Small and Large Cannulated Screws are substantially equivalent to the predicate devices with respect to physical/technical and material characteristics.

Sterilisation Information: The devices are distributed in non sterile, recommendations for sterilization are contained in package insert. Note: These devices are sterilised by end users utilizing the approved/outlined guidelines found in the AAMI Guideline "Good Hospital Practice: Steam Sterilisation and Sterility Assurance" and in ANSI/AAMI/ISO 11737 guidelines to achieve the acceptable Sterility Assurance Level (SAL).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 9 2002

Dipl.-Ing. Christian Abel
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Research & Development
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12099 Berlin
Germany

Re: K021233
Trade/Device Name: aap Small and Large Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 5, 2002
Received: September 10, 2002

Dear Mr. Abel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K021233

Device Name: *aap* Small and Large Cannulated Screw System

Indications for Use:

The *aap* Small and Large Cannulated Screw System is intended for use over a guide pin or wire for bone fracture fixation and bone fragment fixation. *aap*'s washers may be used with the screws in certain applications.

- Minimally invasive fracture / joint reconstructions
- Additive osteosynthesis for complex joint fractures
- Multiple- fragment joint fractures
- Femoral neck and femoral head fractures
- Femoral supracondylar fractures
- Tibial plateau fractures
- Simple metaphyseal fractures
- Simple epiphyseal fractures
    - Fractures of the head of the humerus
    - Fractures of the head of the tibia
    - Cooper fractures of the tibia
    - Fractures of the radius
- Fractures of the wrist, ankle, elbow and shoulder
- Scaphoid fractures and other fractures of the hand
- Metatarsal fractures and other fractures of the foot
- Ligament fixation of the proximal humerus
- Fractures of the acetabulum
- Fractures of the dorsal pelvic ring
- Condylar fractures
- Peadiatric epiphyseal and metaphyseal fractures
- Ligament avulsion injuries (Apohysis)
- Fractures of small joint bones
    - Malleolar fractures
    - Navicular fractures
- Fractures of the calcaneus and talus
- Arthrodesis of the ankle joint
- Avulsion fracture and metatarsl V
- Fractures of the tarsal region

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021233